



Procedural Reference Guide

Version 7.0
March 28, 2012

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Important Pre-Visit Reminders

Several days before the visit

- Place ice BRIX in the freezer for at least 48 hours prior to visit.
- Verify closest FedEx location and directions.
- Check inventory and order supplies as necessary.
- Perform weekly Quality Control Check with glucose test strips and urine QC solution.

The day before the visit

- Charge laptop and Android batteries.
- Charge blood pressure monitor.
- Check batteries in the scale and flashlight.
- Call the participant to remind them of the visit and to collect a full cup of first morning urine. Also remind them to gather all medications, do not to eat or drink, or take their lung medication prior to the visit, if possible.
- Map route and verify directions to the participant's home.
- Restock supplies in HVA toolbox, as necessary.

The day of the visit

- Locate and bring GuLF Photo ID badge and lab jacket to visit.
- Pack the Android car charger.
- Pack power cord for laptop and blood pressure monitor.
- Retrieve ice pack and place in home visit kit.
- Pack Home Visit Kit and HVA toolbox.
- Allow sufficient time to travel to the visit and arrive on time (or early).
- Perform multi-flow and biological calibration check on spirometer.

Order of Home Visit Activities

1. Determine GPS location of participant's home (before leaving car), save reading to Android notes.
2. Verify that you are at the correct address.
3. Retrieve equipment from vehicle.
4. Administer Informed Consent.
5. Verify that first morning void urine specimen was collected (if not have participant attempt to collect one now or have him/her begin drinking water).
6. Measure and record blood pressure and resting heart rate*.
7. Measure and record height and weight; calculate BMI*.
8. Measure and record waist and hip circumference.
9. Collect blood specimens or saliva specimen.
10. Collect hair sample.
11. Collect toenail samples.
12. Perform pulmonary function testing.
13. Administer Baseline survey.
14. Process blood specimens.
15. Perform urine glucose testing*.
16. Process urine specimen(s).
17. Collect dust sample(s).
18. Provide medical referral, if applicable (may be done during informed consent as well).
19. Give Gift Card(s) and obtain receipt.
20. Pack up HVK and clean-up.
21. Ship HVK.
22. Upload data.

*Provide medical referral, if needed

Navigation

Equipment

- Android smart phone
- Android car charger

Procedure

1. Select navigation icon.
2. Select OK when “GPS is disabled Show location settings?” prompts.
3. Select “Use GPS satellites” checkbox to enable GPS receiver.
4. Tap “Back” button.
5. Tap “Type Destination” button.
6. Enter destination (address, city, state).
7. Tap magnifying glass icon.
8. Follow voice directions and routing information on display (to silence the voice directions, select “Menu” and then “Mute”).
9. Select “Exit Navigation” upon route completion.

NOTE: Use of satellite navigation significantly drains battery charge. Ensure that the Android is plugged in to the vehicle charger while navigating to the participant’s home.

GPS Collection of Participant's Home Coordinates

Equipment

- Android smart phone
- Android car charger

Procedure

1. Select Compass application icon.
2. Tap "GPS is disabled! Click here to enable GPS" at top of screen.
3. Select "Use GPS satellites" checkbox to enable GPS receiver.
4. Tap "Back" button.
5. Tap "Add Note" icon.
6. Type note name.
7. *The note name should **not** include the participant's name or any personally identifying information.*
8. Click "Save."
9. To recall coordinates for data entry, click "My Places."
10. Select note name you created for participant.
11. Record the latitude and longitude in data system.
12. Tap "Back" button twice to return to Compass Main Screen.
13. Tap green text (estimated address or coordinates) on top of screen.
14. Select "Use GPS satellites" checkbox to disable GPS receiver.
15. Tap "Back" button.
16. Tap home button to return to home screen.

Alternate Home Coordinate Collection Procedure

If Compass application does not work, use the following procedure:

1. Select GPS Status application.
2. Tap “Use GPS satellites” checkbox under Location and security settings.
3. Tap the “Back” button.
4. Wait for the GPS to activate and achieve a fix.
5. Record the latitude and longitude in Degrees, Minutes, Seconds on a piece of paper (note).
6. *The note should **not** include the participant’s name or any personally identifying information.*
7. Save the note to transpose the data when prompted in the Specimen Collection Survey.
8. Tap the “Home” button.
9. Tap the “Menu” button.
10. Tap the Location & security option.
11. Uncheck the “Use GPS satellites” box.
12. Tap the “Home” button.

Administering Informed Consent

Documents

- Informed Consent Form booklet (ICF) - 2 copies
- Informed Consent Quick Reference Guide
- Specimen Label Set

Procedure

1. Have participant retrieve ICF and Quick Reference Guide that was included in their Pre-Visit Kit (note if a green dot is on form).
2. Apply the “ICF page 1” label to box on cover of form and the “ICF, page 10” label to lower right corner of the page.
3. Review Quick Reference Guide and respond to any questions.
4. Have participant initial the appropriate space at the top of page 10 (CONSENT FOR DISCLOSURE OF INFORMATION TO DOCTORS AND CLINICS AND FOR HEALTHCARE REFERRALS) to indicate whether or not they have a healthcare provider.
5. In the left-hand column, have the participant indicate if they want abnormal results sent to their current healthcare provider by initialing the space and then provide the healthcare provider’s complete name, address and phone number.
6. If the participant does not already have a healthcare provider (or even if they do) and they indicate that they would like a referral to another provider, locate one (or more) candidates using the Referral application and then write the information on the Referral Form. Note in the data application the index number(s) of the referral(s) provided.
7. If participant is selected as a Quality Assurance candidate, review the POSSIBLE ADDITIONAL SAMPLE COLLECTION section on page 11 and have participant initial whether or not they volunteer to provide additional samples (they must initial one or the other of the indicated spaces).
8. On page 12, PARTICIPANT’S CONSENT TO VOLUNTEER FOR THIS STUDY, record the participant’s study identification number (PID) in the spaces provided.
9. If the participant is able to read and understand the form without any assistance and they agree to participate in the study, have

- them sign and print their name in the space indicated on the left-hand side of the page. Sign and print your name below theirs and record the date of the.
10. If the participant cannot read or requires assistance of another adult, on the right-hand side of the page, have that third person witness that the participant consented to participate by signing and printing their name. The participant must also sign their name (if they are able) or otherwise voluntarily provide some a “mark” (e.g., an “X”). The HVA should print the participant’s name in the space indicated and then sign and print their name and date of the visit.
 11. Place the signed and labeled copy of ICF inside the white document envelope in Home Visit Kit - Do not seal the envelope yet.
 12. Leave the second copy of the informed consent for without the barcoded ID labels with participant.

Informed Consent Issues

- If participant is unable to read, attempt to locate a witness for the informed consent process and read the ICF to participant in the presence of an adult witness. If a witness is not available, reschedule the home visit.
- If the participant refuses to sign the ICF, do not continue the home visit.
- If the participant has signed the consent form prior to the visit, have them initial and date next to their signature. **Do not mark through or use white out to cover the original signature or date.**
- If any information is filled out incorrectly, draw a single line through the incorrect information, then add initials, date and a brief note about the correction.
- If several changes need to be made to the original ICF, a new, blank ICF may be used. Return the original form with new form in the envelope, with a note of explanation.

Blood Pressure and Heart Rate Measurement

Equipment

- GE CARESCAPE V100 blood pressure monitor
- DC power supply cord
- Blood Pressure Results form
- Resting Heart Rate Results form
- Blood pressure cuffs
- Air hose
- Vinyl measuring tape
- CaviWipes

Procedure

1. Have participant sit with legs uncrossed and feet flat on floor.
2. Ensure participant has rested quietly for five minutes.
3. Turn on monitor by pressing blue on/off button.
4. Use measuring tape to determine circumference of arm (preferably, the right arm) at bicep and select recommended blood pressure cuff size.
5. Connect end of air hose with quick release clips to front of monitor and attach selected cuff.
6. Palpate brachial artery midway between shoulder and elbow and place cuff midline, indicated by an arrow and ARTERY, over brachial artery 2-3cm above elbow crease.
7. Press green inflate button.
8. Record blood pressure and resting heart rate measurement in data system and results forms.
9. Collect and record 2 additional measurements for blood pressure and resting heart rate (**use the same arm for all measurements**), allowing 1 minute rest time between each measurement (refer to Blood Pressure Results form and Resting Heart Rate Results form for interpreting the results).
10. Remove cuff from arm and turn off monitor.
11. Disconnect cuff and disinfect with CaviWipe.
12. Complete *Blood Pressure Results* and *Resting Heart Rate Results* forms to give to participant.

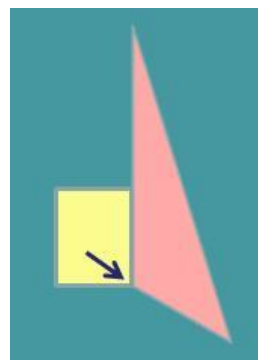
Height Measurement

Equipment

- Steel tape measure
- Drafting triangle
- Body Mass Index Results form
- Post-It notes
- Pen

Procedure

1. Have participant remove shoes.
2. Ask participant to stand with feet touching or as close together as possible, against a flat wall surface or doorframe.
3. Place drafting triangle on top of participant's head with the right angle touching the wall or doorframe.
4. Place a Post-It note on wall with the sticky edge of note touching the side of the triangle and the bottom edge of the note flush with BOTTOM edge of triangle.
5. Draw an arrow on the Post-It note pointing to the CORNER of triangle.
6. Have participant step away from the wall.
7. Use steel tape to measure the distance from the floor to the corner of the Post-It note with the arrow.
8. Record measurement in centimeters on the Post-It note.
9. Repeat procedure two more times.
10. Record calculated average height from the data system onto the *Body Mass Index Results* form.



Weight Measurement

Equipment

- Health-O-Meter, Model 822KL, digital scale
- Body Mass Index Result form

Procedure

1. Have participant remove shoes and any heavy items in their pockets.
2. Place scale on an un-carpeted, flat surface.
3. Turn on scale by tapping lightly with your foot.
4. Verify that scale is measuring in kilograms.
5. Have participant stand on scale and remain still.
6. Wait for the numbers to register.
7. Record result (in kilograms) in data system.
8. Repeat procedure two more times.
9. Record participant's average weight from the data system on the *Body Mass Index Results* form.

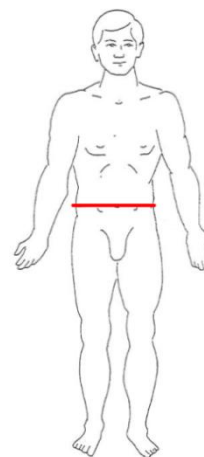
Waist Circumference Measurement

Equipment

- Vinyl measuring tape

Procedure

1. Have participant remove their belt and any bulky clothing items.
2. Have participant stand with weight equally distributed on each foot.
3. Stand at participant's side and place the end of the measuring tape above the hip bone and level with the navel.
4. Have participant hold the end of the tape in place with one hand and turn in one full circle while you hold the other end of the tape.
5. Verify that the tape crosses the naval (see red line) and that the tape is horizontal with the floor (front and back).
6. Have participant take a normal breath, gently exhale, and relax.
7. Take measurement at participant's side by overlapping the reading with the end tip of the tape.



8. Record results in centimeters.
9. Repeat the procedure two more times.

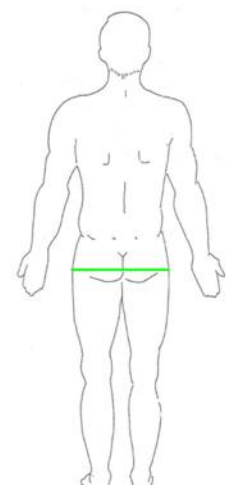
Hip Circumference Measurement

Equipment

- Vinyl measuring tape

Procedure

1. Have participant remove their belt and any bulky clothing items.
2. Have participant stand with weight equally distributed on each foot.
3. Stand at participant's side and place the end of the measuring tape on the hip bone and about two inches below the naval at the maximum protrusion of the buttocks.
4. Have participant hold the end of the tape in place with one hand and turn in one full circle while you hold the other end of the tape.
5. Verify that tape is over the maximum protrusion of the buttocks (see green line) and that the tape is horizontal with the floor (front and back).
6. Have participant take a normal breath, gently exhale, and relax.
7. Take measurement at participant's side by overlapping the reading with the end tip of the tape.



8. Record results in centimeters.
9. Repeat the procedure two more times.

Blood Collection

Equipment

- Hand sanitizer
- Gloves
- Alcohol prep pad
- Tourniquet
- Gauze
- Foam tube holder
- Specimen Transmittal Form
- Micropore tape
- Blood collection set
- Tube holder
- Blood collection tubes
- Adhesive bandage
- Sharps Container
- Specimen Label Set

Procedure

1. Perform venipuncture and collect tubes in the following order:

	Tube	# of Inversions
Tube 01:	10 mL Red top	5x
Tube 02:	10 mL Red-top	5x
Tube 03:	10 mL Lavender-top	8-10x
Tube 04:	6 mL Yellow-top	8-10x
Tube 05:	6 mL Royal blue top	8-10x
Tube 06:	2 mL Lavender-top	8-10x
Tube 07:	6 mL Lavender top	8-10x
Tube 08:	PAXgene RNA	10x

2. If the participant has volunteered to provide Quality Assurance Specimens, collect the four additional QA tubes BEFORE collecting the PAXgene tube (see QA Blood Collection instructions for tube order on following page).
3. PAXgene tube must always be collected last and held vertical and below participant's arm to avoid backflow of the additive (if the participant is a QA candidate, collect QA tubes prior to PAXgene).



4. Apply the appropriate barcoded specimen ID labels from the Specimen Label Set.
5. Record in data system and on the Specimen Transmittal Form.
6. Allow the two red-top tubes to clot for at least 30 minutes prior to processing.

Quality Assurance Blood Collection

Equipment

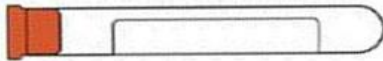
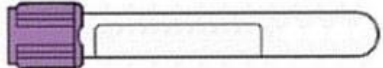
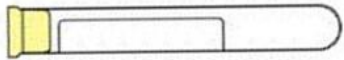
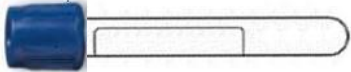
- Blood Collection supplies above
- One 10 mL red top tube
- One 10 mL lavender top tube
- One 6 mL yellow top tube
- One 6 mL royal blue top tube
- Two biohazard bags with

Preparation

1. Designated QA HVAs will collect QA samples from Active or Biomedical Surveillance Subcohort participants when prompted by Project Staff or their Regional Manager (collect QA samples from Active participants every other week and collect QA samples from BSS participants weekly).
2. Once prompted to begin approaching participants about providing QA samples, the HVA will ask every participant visited if they would be interested in providing the needed extra samples until someone accepts. This is done during the informed consent process.
3. Note in the Baseline Questionnaire whether a participant was approached about providing QA samples and whether or not (s)he volunteered to provide the additional specimens.
4. If the participant was asked to provide QA samples, have them note their response about whether they volunteer to provide the samples or not by initialing the appropriate space on page 11 of the Informed Consent Form booklet.

QA Blood Collection Procedure

5. Collect QA specimens at the same time the other blood specimens are collected, and **before** the final PAXgene tube has been collected. If necessary, these specimens can be collected from a second “stick” if blood flow ceases before all needed specimens are collected.
6. Collect **QA blood tubes** in the following order before the PAXgene tube has been collected:

	Tube	# of Inversions
QA 01: 10 mL Red top		5x
QA 02: 10 mL Lavender-top		8-10x
QA 03: 6 mL Yellow-top		8-10x
QA 04: 6 mL Royal blue top		8-10x

7. Apply QA Specimen ID labels from Specimen Label Set.
8. Dispose of blood collection set (butterfly), but not the tube holder, in the sharps container.
9. Place Tubes QA 01, QA 02 and QA 04 in a separate biohazard bag with absorbent pad and put the bag in the **lower chamber** of the HVK box. Place the yellow-topped Tube QA 03 in the same biohazard bag as the yellow-topped Tube 04 and put the bag in the **upper chamber** of the HVK box.

*Note: See page 31 for Urine QA Specimen Processing

Saliva Collection

Equipment

- Gloves
- Oragene DNA collection kit
- Sugar packet
- Biohazard bag

Procedure

1. **SHOULD ONLY BE PERFORMED IF BLOOD CANNOT BE COLLECTED. If you are able to get any blood at all, a saliva sample is not needed.**
2. Put on gloves.
3. Remove blue cap from collector cup (the cap contains a preservative liquid behind plastic film).
4. Give collector cup to participant.
5. Have participant spit saliva into collector cup until saliva reaches indicated fill line on cup (if participant has difficulty generating enough saliva, have them briefly place about ¼ tsp. of sugar on their tongue).
6. Have participant place collector cup on absorbent pad.
7. Tightly screw cap onto collector cup, which will release the preservative into the saliva specimen.
8. Invert collector cup for at least 10 seconds to mix saliva with preservative.
9. Place the Saliva (SAL) Specimen ID label on the bottom of collector cup.
10. Place collector cup inside biohazard bag with absorbent pad.
11. Seal biohazard bag.

Hair Collection

Equipment

- Gloves
- Hair clamps (2)
- Comb
- Unwaxed dental floss
- Alcohol prep pad
- Foil sheets
- Snack-size Ziploc bag
- Card stock ("2.5 x 6")
- Desiccant pack
- Specimen Label Set

Procedure

1. Put on gloves.
2. Cut a 6 inch piece of dental floss and tie a slipknot.
3. Obtain a sheet of foil from the toolbox.
4. At back of head where the skull joins the spine, use the comb to separate hair and fasten to each side of the head with hair clamps.
5. Separate a lock of hair at least 1 centimeter long and the thickness of a pencil at the nape of neck.
6. Place dental floss slip-knot around the strand of hair and cinch.
7. Cut hair close to scalp between dental floss and scalp.
8. Place lock of hair on foil.
9. Fold foil lengthwise and fold ends of foil so that foil packet matches the size of card stock.
10. Mark an X on foil at the end where the hair was closest to scalp.
11. Apply Hair ID label from Specimen Label Set to foil packet.
12. Place labeled foil packet in Ziploc bag with card stock and desiccant pack. Ensure that the label is visible through the bag.
13. Seal Ziploc bag.
14. Use alcohol pad or CaviWipe to disinfect comb, scissors, and hair clips.



Toenail Collection

Equipment

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Gloves • Metal toenail clippers • Nail polish remover • Collection envelope • Desiccant packet | <ul style="list-style-type: none"> • Specimen Label Set • Alcohol prep pad • Participant Collection Instruction Sheet • Business Reply Envelope |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Procedure

1. Put on gloves.
2. Have participant retrieve personal toenail clippers (if unavailable, use clippers in tool kit).
3. Have the participant clip toenails (clip for them, if requested).
4. Have participant place clippings into collection envelope.
5. Apply moisture to the envelope using a damp gauze pad or fresh alcohol pad and seal.
6. Apply Toenails Specimen ID label from the Specimen Label Set to envelope
7. Use alcohol pad or CaviWipe to disinfect metal clippers.

Procedure for Participant Collection of Toenails

1. Should only be used if cannot collect toenails during home visit.
2. Write HVA # on the GuLF STUDY Business Reply Mail envelope, below the return address.
3. Apply Toenails Specimen ID label from the Specimen Label Set to the envelope.
4. If a BSS participant, apply green dot to collection envelope.
5. Give the collection envelope, Toenail Collection Instruction sheet, a nail polish remover packet (if female and/or wearing toenail polish), and the GuLF STUDY Business Reply Mail envelope to the participant.
6. Review the instruction sheet with the participant.

Pulmonary Function Testing

Equipment

- Laptop and Easy on-PC Spirometer
- Spirette and nose clips

*Exclusion Criteria:

1. Systolic blood pressure reading greater than or equal to 180
2. Diastolic blood pressure reading greater than or equal to 110
3. Resting heart rate greater than or equal to 120 bpm
4. Surgical procedure on eye, chest or abdomen within the last 3 months
5. Hospitalized for heart disease or stroke within the last 3 months

Procedure

1. Complete PFT exclusion criteria questions in data system.
2. Launch both instructional videos from desktop and provide commentary on each explaining preparation and maneuvers. Emphasize filling the lungs completely, blasting out as hard and as fast as possible, and completely emptying the lungs. Demonstrate the maneuver incorporating these concepts and reemphasize the 3 main steps for successful trials.
3. Enter participant information and complete ethnicity according to Table 1 (see following page).
4. Have participant sit down in a hard, straight back chair (e.g., a dining room chair and NOT on a couch or a cushioned lounge chair), remove any items from mouth, and apply nose clip.
5. Demonstrate Spirometry using HVA Spirette and nose clips. Emphasize filling the lungs completely, blasting out as hard and as fast as possible, and completely emptying the lungs.
6. Have participant perform PFT using participant's Spirette and nose clips and vigorously coach/encourage them to "BLAST OUT!" and "BLOW, BLOW, BLOW...until the lungs are empty"
7. In the event of error message, refer to Table 2 (see following page) for recommended actions.
8. Collect 3 successful maneuvers, allowing participant to rest between each maneuver.

9. Do not perform more than 8 maneuvers.
10. Disinfect handset of spirometer using CaviWipe and return handset to protective carrying case.

Table 1. Ethnic Value Selections for Participants of Mixed Race

Father's Race	Mother's Race			
	African-American	Anglo-Caucasian	Asian-American	Hispanic-American
African- American	Black	Caucasian	Caucasian	Hispanic
Anglo-Caucasian	Caucasian	Caucasian	Caucasian	Hispanic
Asian- American	Caucasian	Caucasian	Caucasian	Hispanic
Hispanic- American	Hispanic	Hispanic	Hispanic	Hispanic

Table 2. Spirometry Quality Messages

Message	Recommended Action
Don't hesitate	The participant must exhale all air at once and not exhale in short bursts.
Blast out faster	The participant must exhale more explosively and as firmly and quickly as possible.
Blow out longer	The participant stopped exhaling too early. The participant must exhale still further and force as much air as possible out of his or her lungs.
Test Abrupt End!	The participant stopped exhaling too early. The participant must exhale still further and force as much air as possible out of his or her lungs.
Good effort, do next	Good trial. Only one to two more good trials and the test is complete.
Do not start too early!	Instruct the participant to wait until the baseline setting is finished and the device signals that the trial can start ("Start maneuver..")
Cough detected. Try again	Instruct the participant to avoid coughing during the first second. Repeat the test.
Deeper breath	The test differs greatly from previous tests. The participant can inhale even more deeply and exhale even more air.
No maneuver detected!	Instruct the participant to perform the maneuver according to its definition.
Session complete! Good job!	The test is complete. An adequate number of good tests are available.

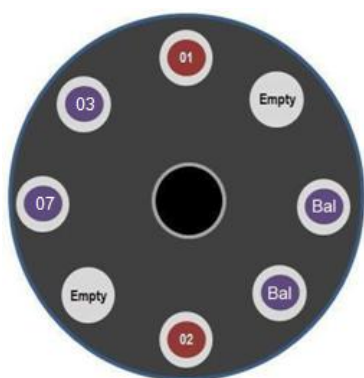
Blood Centrifugation

Equipment

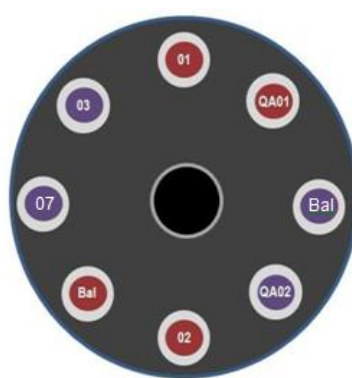
- *Specimen Transmittal Form*
- Specimen Label Set
- Centrifuge
- Gloves
- 10 mL red-top balance tube
- 10 mL lavender-top balance tube
- 6 mL lavender-top balance tube
- Transfer pipettes

Procedure

1. Complete *Specimen Transmittal Form* and apply the STF ID label (if Biomedical Surveillance Subcohort, affix fluorescent green dot sticker to upper right corner of form).
2. Allow red-top tubes to clot for at least thirty minutes before centrifuging.
3. Place the centrifuge on an absorbent pad or old newspaper on level surface near an electrical outlet. The centrifuge can be set on the floor or on the toolbox if there is no counter or tabletop space available. *Make sure that children or pets do not bump into it if it is on the floor.*
4. After clotting, ensure that like tubes (blood and balance) have approximately the same volume of fluid in them and then position tubes in centrifuge along with the appropriate balance tubes according to the following diagram:



Rotor without QA tubes
(4 specimens, 2 balance)

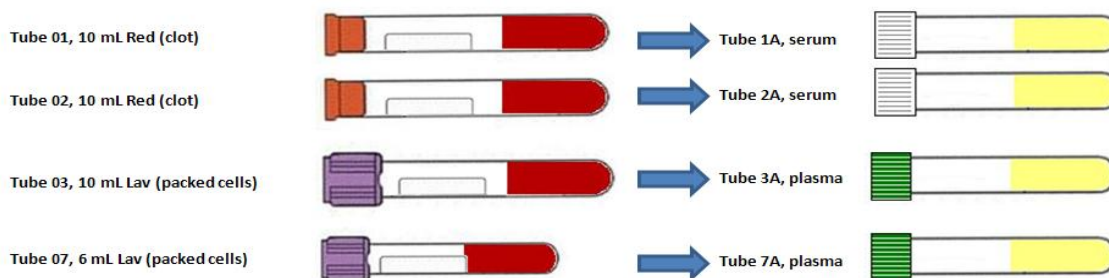


Rotor with QA tubes
(6 specimens, 2 balance)

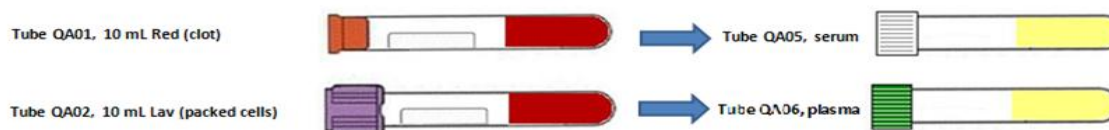
5. **CENTRIFUGE TUBES MUST BE PROPERLY BALANCED to prevent damage to the specimens and to the centrifuge.** If the centrifuge makes a loud vibrating noise when started up, **TURN IT OFF IMMEDIATELY!** Wait for the rotor to stop turning and then rebalance the rotor.

6. Centrifuge the tubes for at least 15 minutes. Gently remove tubes after centrifugation to avoid disturbing the serum or plasma and red cell interface.
7. Use transfer pipette to carefully aspirate serum from top portion of red-top tubes and dispense serum into corresponding white aliquot tubes (see figure on next page).
8. **Tightly screw white caps on tubes** and apply ID labels. Apply Parafilm to the top of the tube to secure lids
9. Carefully return stopper to red-top tubes by twisting them to reseal the stopper so that the stopper touches the rim of the tube. Apply Parafilm to secure stoppers in place.
10. Use transfer pipette to carefully aspirate plasma from top portion of lavender-top tubes and dispense plasma into corresponding green aliquot tubes.
11. **Tightly screw green caps on tubes** and apply ID labels. Apply Parafilm to the top of the tube to secure lids.
12. Carefully return stopper to lavender-top tubes by twisting until they are fully seated. Apply Parafilm to secure stoppers in place.
13. Remove balance tubes from centrifuge and secure the rotor with a piece of foam and then lock the lid.
14. Return centrifuge to the HVA toolbox.
15. Wipe down the surface under and around the centrifuge with a disinfectant CaviWipe.

Typical Specimen Aliquoting



QA Specimen Aliquoting



Centrifuge Emergencies

Procedure

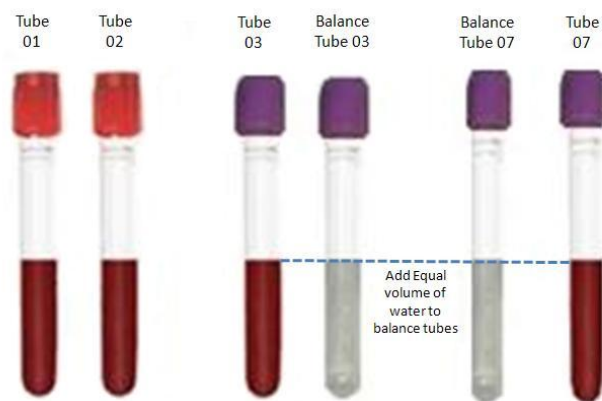
If you suspect for any reason that the centrifuge is not running properly or that specimens may have been damaged while the centrifuge is running (i.e, something sounds like it is rattling around inside), **TURN THE CENTRIFUGE OFF IMMEDIATELY AND DO NOT OPEN THE CENTRIFUGE.**

1. After turning off the centrifuge, unplug it and proceed with other home visit activities, while allowing the interior environment of the centrifuge to stabilize for 30 minutes.
2. After 30 minutes, and while wearing gloves, **carefully** open the centrifuge to observe what happened.
3. If it appears that one or more of the specimen or balance tubes have broken, ***do not reach inside the centrifuge.*** Skip to Step 7; otherwise go to Step 4.

If the rotor was unbalanced:

4. If nothing appears to be broken, check each tube in the rotor to verify that they are intact and are properly counter-balanced.
5. If the rotor was not properly balanced refer to Step 4 in the Centrifugation Procedure and balance properly.

6. Verify that opposite tubes have approximately the same volume of fluid in them. If the balance tubes do not have the same volume of water as do the blood tubes (for example, if the blood tube was not completely filled during collection) remove the



stopper from the appropriate balance tube and use a plastic transfer pipet to remove some water so that the fluid level in the balance tube is the same as it is in the blood tube. (NOTE: you will need to prepare another balance tube or refill this one to its former level for future home visits). Proceed with Step 4 in the Centrifugation Procedure.

If there are broken tubes:

7. Retrieve a new absorbent pad from your supply tub and unfold it. Starting with the longest edge of the pad, loosely roll the pad up so that the white side of the pad is facing out and blue plastic liner is inside the roll.
8. Curve the rolled-up pad around and **CAREFULLY** place it on top of the rotor so that it can absorb any fluid (water or blood) from the broken tubes. Do not use your hands to force the pad down inside the centrifuge chamber.
9. Close and latch the centrifuge lid and then tape around the edge of the lid with packing tape so that nothing will leak out.
10. Thoroughly wipe the exterior of the centrifuge and the surface where it was sitting with one or more large Caviwipes from the container in the supply tub (do not use one of the smaller pre-packaged wipes from the home visit kit).
11. Retrieve two heavy-duty trash bags from your supply tub. Place the centrifuge inside one, seal it and then place this sealed bag inside the second bag and seal it also.
12. Take the centrifuge out to your vehicle and secure it in the trunk or back seat so that it will not tip over.
13. Proceed with any remaining home visit activities.
14. If the red top and lavender top specimens are lost, ask the participant if you can return at some future time and recollect the damaged specimens. If the participant agrees, set up a return date to recollect these specimens and continue with the visit.
15. If specimens were lost or damaged, complete an incident report in CAPI to document what occurred.
16. Contact your Regional Manager for further instructions.



Urine Glucose Testing

Equipment

- Gloves
- Urine collection kit
- Glucose testing reagent strips
- Urine Glucose Results form
- Transfer pipette
- Gauze pads
- Specimen Label Set
- Specimen Transmittal Form

Procedure

1. Put on gloves.
2. Record urine information on the Specimen Transmittal Form.
3. Use a transfer pipette to draw up several drops of urine.
4. Hold a Glucose reagent strip above a gauze pad and apply one drop of urine to the reagent pad. Be sure that the entire pad is covered and then immediately turn the strip on edge and touch the edge of the pad to the gauze to wick off excess urine.
5. Wait exactly 30 seconds (use your watch or Android timer) and then compare the color of the reagent pad with the comparison chart on Diastix bottle.
6. Record urine glucose results in the data system and on the *Urine Glucose Results* form to give to the participant.
7. Explain the urine glucose testing results to the participant.
8. Discard trash in a Ziploc bag.

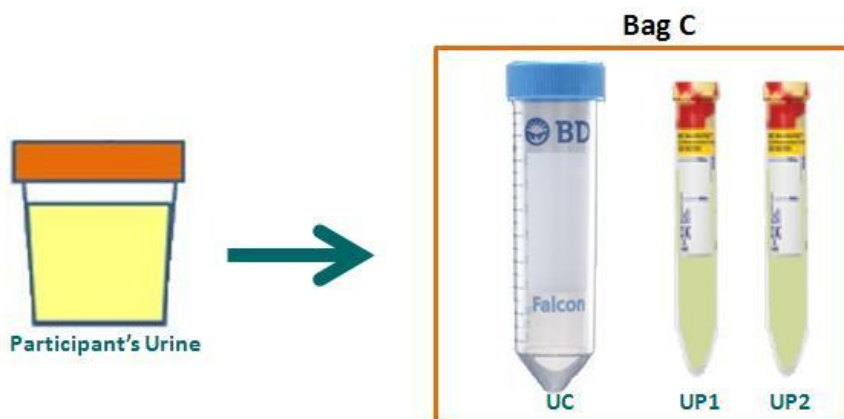
Urine Processing Procedures

Equipment

- Gloves
- 1 empty urine collection cup
- 1 Biohazard bag
- 50 mL Falcon Urine Tube
- Urine Transfer Straw kit
- Red/Yellow UA Preservative Tube
- Sharps container
- Specimen Label Set

Procedure for Processing Active Subcohort Urine Specimens

1. Using the Urine Transfer Straw kit, fill the UA Preservative Tube with urine from the urine cup.
 2. After filled, remove tube from holder and invert 8-10 times.
 3. Repeat Steps 1-2 using a second red/yellow UA Preservative Tube.
 4. Discard the used Urine Transfer Straw in the sharps container with the large end pointed down.
 5. Apply the “UP1” and “UP2” ID labels to the two UA Preservative Tubes.
- *Note: If the participant has consented to QA Specimen Collection, skip the following steps and follow the instructions on page 32.**
6. Pour the remaining urine into the 50 mL Falcon Urine Tube.
 7. Apply the “Unpreserved Urine” ID label (“UC”) to the 50 mL Falcon Urine Tube.
 8. Record urine collection type (Random or FMV), as well as date, time and volume of original urine collection on Specimen Transmittal Form.
 9. Place the 50 mL Falcon tube and the two UA Preservative tubes in one biohazard bag (see figure below). Place this bag in the bottom chamber of the HVK box.

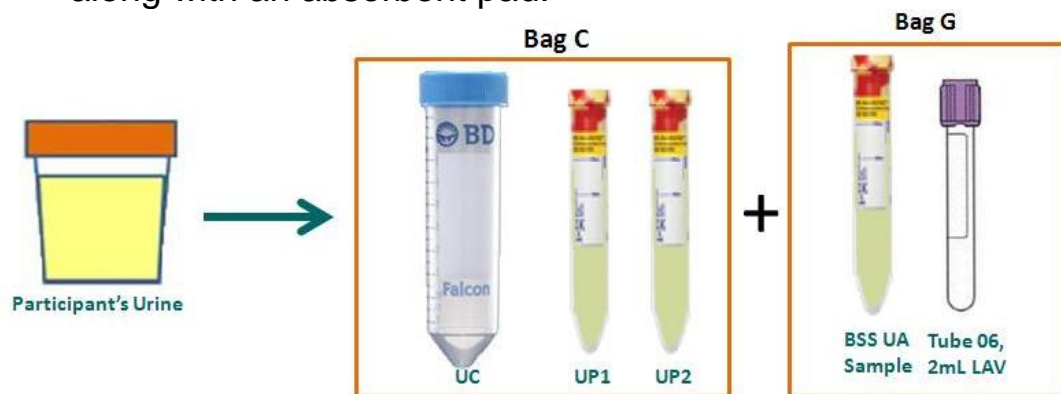


Procedure for Processing Biomedical Subcohort Urine Specimens

1. Use the Urine Transfer Straw kit to fill 3 red/yellow top UA Preservative Tubes with urine from the urine cup.
2. Invert each tube 8-10 times after filling.
3. Apply the barcode “UP1” and “UP2” ID labels to two UA Preservative Tubes. Then, apply the “BSS UA Sample” ID label to the third UA Preservative Tube.

***Note: If the participant has consented to QA Specimen Collection, skip steps 4-7 and follow the instructions on page 32.**

4. Discard the used Urine Transfer Straw in the sharps container with the large end pointed down.
5. Pour the remaining urine into the 50 mL Falcon Urine Tube and apply the “Unpreserved Urine” ID label (“UC”).
6. Record urine collection type (Random or FMV), as well as date, time and volume of original urine collection on Specimen Transmittal Form.
7. Place the 50 mL Falcon tube and the two UA Preservative tubes labeled “UP1” and “UP2” in one biohazard bag. Place this bag in the bottom chamber of the HVK box.
8. Place Tube 06 (the 2 mL lavender-top tube) and the red/yellow top Urinalysis transfer tube (BSS UA Sample) in a biohazard bag (Bag G) along with an absorbent pad.



9. Fill in the urine info in the box in the upper right corner of the form:

- Fasting/Nonfasting
- Urine Collection Time
- Original Urine Volume

10. Fill in the requested information in the blue-shaded boxes (since this is a 3-page pressure sensitive form, press hard so the information transfers to the last page):

- Record times **using the 24-hour or military clock** (see right).
- Record the participant's initials only.
- Enter the Participant ID # (NOT the HVK #) in the space for "Patient Number."



11. Fold up **Copy 1** and **Copy 2** of the LabCorp TRF and place them in the outer pouch of biohazard bag.

12. Put the LabCorp TRF label on the outside of the biohazard bag.

13. Put one of the Spare barcoded labels on **Copy 3**. Fold up **Copy 3** and place it in the Document Envelope along with the Informed Consent Form and Gift Card Receipt.

Quality Assurance Urine Processing

Equipment

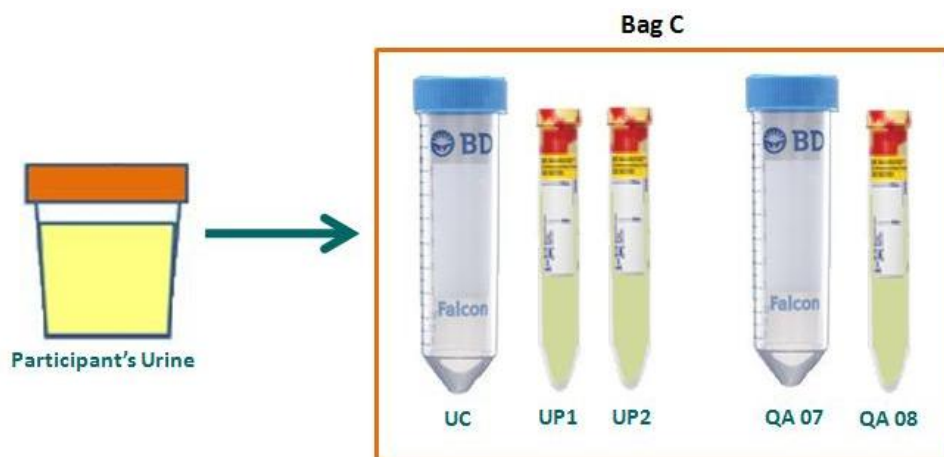
- Gloves
- 50 mL Falcon Tube
- Red/Yellow UA Preservative Tube
- Sharps container
- Specimen Label Set
- Biohazard Bag w/absorbent pad

***Note:** If doing a QA visit, these procedures should be done at the time of the general Urine Processing Procedures on pages 29-30.

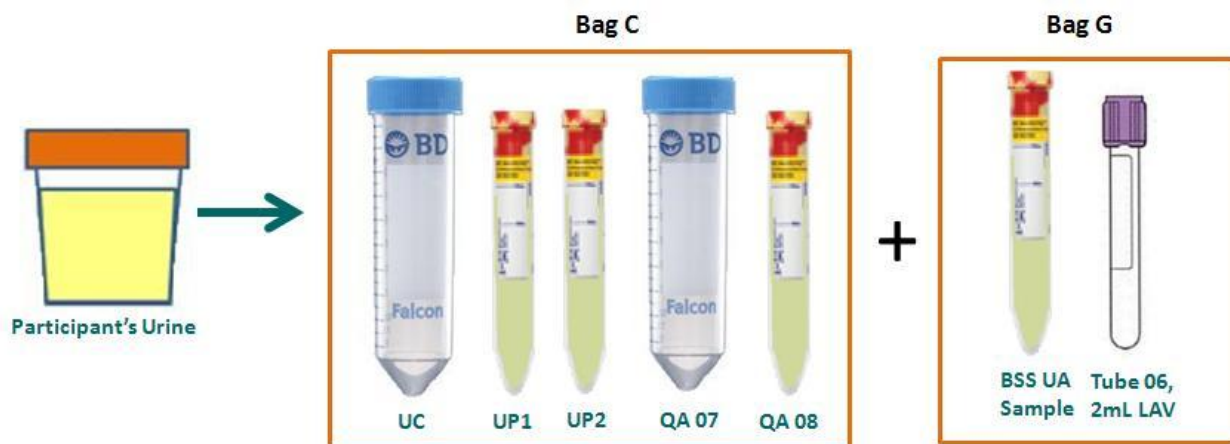
QA Urine Processing Procedure for Active and Biomedical Subcohorts

1. Draw up an additional urine aliquot into a red/yellow UA Preservative Tube. Label this tube with the “QA 08, Preserved Urine” label.
2. Equally divide the remaining urine specimen into two 50 mL Falcon Tubes.
3. Label one tube with the “Unpreserved Urine” (UC) label and the other tube with the “QA 07, Unpreserved Urine” label from the label set.
4. Place both 50 mL Falcon tubes and the UA Preservative Tubes labeled “UP1”, “UP2”, and “QA 08, Preserved Urine” in one biohazard bag, Bag C (see Figure 1 below). Place this bag in the bottom chamber of the HVK box.
5. Record urine QA specimen collection information in data system and on the Specimen Transmittal Form. Note that the participant was given a \$10 gift card on the Gift Card Receipt Form.

Figure 1. QA Active Subcohort



***Note:** If in the QA Biomedical Subcohort, follow steps 8-13, beginning on page 30, for instructions on how to bag the LabCorp specimens. Your bags containing the urine aliquot samples should look like the figure below.



Alcohol Wipe Dust Collection

Equipment

- Alcohol swabs (8)
- Ziploc bag
- Specimen Label Set
- Specimen Transmittal Form

Collection Surface

- Select three different sampling surfaces from three different rooms. Surfaces should be door frames, tops of cabinets, tops of picture frames and/or the top of the refrigerator. Selected surfaces should be at least ½ inch wide and x 36 inches long or 18 square inches.
- Use two alcohol pads to perform test wipes in an inconspicuous place to ensure the alcohol does not damage the selected sampling surfaces.
- Dispose of test wipes.

Procedure

1. Wipe back-and-forth across selected surface with 2 separate alcohol wipes.
2. Place wipes in Ziploc bag and write the number of wipe on the outside of the bag with a felt tip pen.
3. Apply the **Dust (Alcohol)** specimen ID label to the Ziploc bag
4. Record sample collection information (# wipes collected) in data system and on the Specimen Transmittal Form.

3. Assemble vacuum wand and extensions and connect to power supply
4. Set timer on Android phone for 2 minutes (or use the time determined from the table above if not using the template)
5. Obtain nylon mesh filter and place it inside DUSTREAM Collector
6. Place collector on end of the vacuum extension wand
7. Start vacuum and timer and vacuum the bed grid first
8. Move extension wand with collector firmly but slowly, forward-and-back, covering the whole grid in this direction for 30 seconds and then vacuum left-and-right covering the whole grid again in this direction for another 30 seconds
9. After 60 seconds, ***and without shutting the vacuum off***, switch to vacuuming the floor in a similar manner; 30 seconds in each direction
10. When timer ends hold the vacuum wand straight up in the air and (so the filter does not fall out) and turn vacuum off
11. Remove the filter and place it in the 1" x 3" Ziploc bag and apply the Dust (Vacuum) ID label from the Specimen Label Set
12. Replace any of the participant's personal belongings that were moved during vacuuming procedure
13. Wash DUSTREAM Collector in the sink with warm soap and water

Medical Referral

Equipment

- Medical Referral Database
- Medical Referral Form

Important

Provide a medical referral to participants who have indicated that they would like one, either during the informed consent process or at any other time during the visit such as after providing them with abnormal blood pressure, heart rate, urine glucose, and/or BMI results reporting or at any other time during the visit.

Procedure

1. Open Medical Referral Database.
2. Select state and county (or parish) or referral type.
3. Sort list by facility, city, or type by clicking on appropriate headings.
4. Review near-by facilities with participant.
5. Select desired facility.
6. Complete *Medical Referral Form* with information displayed.
7. Provide up to three referrals.
8. Log information into data entry system to note which facilities were referred to the participant.
9. Give the completed *Medical Referral Form* to participant.

Specimen Packaging

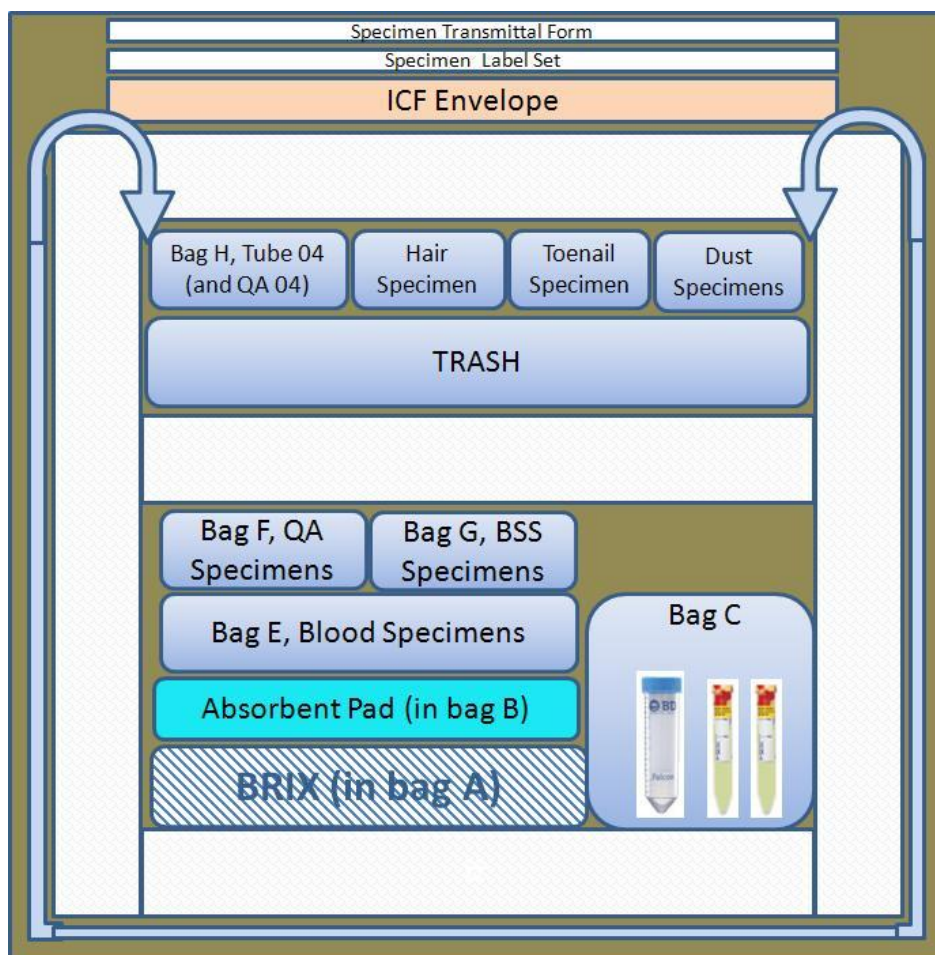
- Package specimens according to the following table (start at bottom of the table and work your way up)

Bag	Bag type, Source	Contents		HVK Chamber
H	BH, HVK	Blood Collection Tube 04, 6 mL Yellow-top tube(s), and Tube QA 04, 6 mL Yellow-top, if collected		Upper chamber with no ice pack
N/A	(No Bag)	Hair specimen bag, Toenail specimen envelope, Dust sample bag(s) (alcohol and vacuum). Place separately in box; not combined in one Ziploc		
TRASH	Zip, HVK	Trash from home visit activities. DO NOT INCLUDE SHARPS!		
Foam Divider (with tourniquet as pull-strap)				
G	BH, Toolkit	Biomedical Surveillance Subcohort Participants only: BSS UA Sample (8 mL red/yellow top UA Preservative Tube) Tube 06, 2 mL LAV for CBC testing		Lower with Frozen BRIX
F	BH, Toolkit	Blood Collection Tubes: Tube QA 01, 10 mL RED Tube QA 02, 10 mL LAV Tube QA 03, 6 mL BLUE	Aliquot tubes: Tube QA 05, serum, (white cap) Tube QA06, plasma (green cap)	
E	BH, HVK	Blood Collection Tubes: Tube 01, 10 mL RED Tube 02, 10 mL RED Tube 03,10 mL LAV; Tube 05, 6 mL BLUE Tube 06, 2 mL LAV (Active Follow-up Sub-cohort Participants only); Tube 07, 6 mL LAV Tube 08, PAXgene RNA	Aliquot tubes: Tube 1A, serum (white cap) Tube 2A, serum (white cap) Tube 3A, plasma (green cap) Tube 7A, plasma (green cap)	
		Saliva Specimen (if unable to collect blood)		
D		This bag has been removed.		
C	BH, HVK	All Urine Aliquot Tubes (including QA tubes if applicable)		
B	Zip, HVK	Absorbent Pad in Ziploc bag to act as insulator and cushion		
A	Zip, HVK	Frozen Re-FREEZ-R-BRIX		

*BH = Biohazard bag; Zip = Ziploc bag; HVK = Bags are found in Home Visit Kit; Toolkit = Obtain bags from toolkit supplies

- Place Ziploc Bag A containing the frozen BRIX in bottom of box.
- Place neatly-folded used blue absorbent pad inside Ziploc Bag B on top of ice pack.
- Place Bag C, urine aliquot tubes, upright in the bottom of the box between foam wall and BRIX.
- Roll up Bag E (and Bag F, if QA blood specimens collected) and secure with rubber band, and place on top of absorbent pad.
- If Biomedical Surveillance Subcohort, complete LabCorp Test Requisition Form and insert into outer pouch of Bag G.
- Roll up bag G and secure with rubber band and insert into lower chamber of box.

8. Wrap used tourniquet around one of the foam lids and insert firmly into HVK box.
9. Place TRASH bag on top of foam divider (NO SHARPS). Non-contaminated paper and wrapper trash can be disposed of in the participant's trash can.
10. Insert Hair specimen bag, the Toenail envelope, and the Dust sample bag(s) (Alcohol and Vacuum) into the upper chamber **without** placing them into another Ziploc bag.
11. Place bag H with the yellow-top tube(s) in the very top of the upper chamber. Neatly tuck plastic containment bag into chamber and insert the upper foam lid.
12. Insert the signed Informed Consent Form and Gift Card Receipt and Copy 3 of the LabCorp Test Requisition Form (if Biomedical Surveillance Subcohort specimens collected).
13. Place sealed envelope on top of upper foam lid.
14. Place used Specimen Label Set on top of envelope.
15. Fold Specimen Transmittal Form and place on the very top of the container, so that it is the first thing seen when the box is opened.
16. Seal box with packaging tape (but do not over-tape!). Use FedEx preferred "H" taping method; across the flap and down the edges.



Gift Card Receipt

Equipment

- \$50 American Express Gift Card
- Gift Card Receipt form
- \$10 WalMart gift card (for QA samples)

Gift Card Receipt

1. Record the visit date.
2. Check the box to indicate that the participant received a \$50 AmEx gift card.
3. If applicable, check the box to indicate that the participant received a \$10 WalMart gift card for a QA sample.
4. Record the gift card number(s).
5. Record the participant ID# and address.
6. Have the participant sign and print their name.
7. Sign the receipt on the witness line.
8. Place the original signed copy of the form in the envelope with the ICF and package with the specimens.

Give the gift card(s) and the second (carbon) copy of the receipt to the participant.

Returned Documents Quality Assurance Checklist

HVA Name: _____ HVA Number: _____

<p>Apply Spare 10 label from returned label set here</p>

HVAs are instructed to return the signed and labeled *Informed Consent Form* in a sealed document envelope along with the Gift Card *Receipt*. In addition, they are to return the completed and labeled *Specimen Transmittal Form* and used *Specimen Label Set* in the kit as well. The following checklist evaluates these returned documents.

Specimen Transmittal Form	
_____	The CPL returned the Specimen Transmittal form to SRA
_____	HVA ID is written on the form

_____	The barcoded Specimen ID label on the form matches the ID in the upper right corner of the envelope

_____	Biomedical Surveillance and QA check matches informed consent and gift card receipt

_____	Date of visit matches date on ICF

Informed Consent Form	
_____	The HVA returned the ICF in the sealed envelope
_____	Participant and HVA initialed and signed and dated form correctly in all consent sections

_____	A witness signature is present for those participants who have had the consent read to them

_____	The date on the form matches the date of the visit

_____	The correct labels are applied to pages 1 and 10

Specimen Label Set	
_____	The used Label Set was returned
_____	Correct version of the label set was used

Gift Card Receipt	
_____	The HVA returned the Gift Card Receipt with original signatures
_____	Participant and HVA signed and dated gift card receipt in all sections

_____	Correct gift card amount on receipt is checked for BSS and QA

_____	AmEx Gift Card serial number on receipt matches the Gift Card serial number on the envelope label

_____	The QA Gift Card serial number matches the serial numbers assigned to this HVA.

Results Reporting

Urine Glucose Results Form

1. Complete participant name and visit date.
2. Ask participant the two “Assessment of Diabetic Symptoms” questions.
3. Record urine glucose results.
4. Complete table under *Interpretation and Advice* by circling appropriate squares.
5. Identify and read the corresponding advice.
6. Leave form with participant.

Blood Pressure Results Form

1. Complete participant name and visit date.
2. Record three blood pressure measurements.
3. Record computer-calculated blood pressure average.
4. Place a checkmark (✓) in the row that corresponds with the calculated average BP result.
5. Review results and advice.
6. Leave form with participant.

Resting Heart Rate Results Form

1. Complete participant name and visit date.
2. Record three heart rate measurements.
3. Record computer-calculated heart rate average.
4. Place a checkmark (✓) in the row that corresponds with the calculated average heart rate result.
5. Review results and advice.
6. Leave form with participant.

Body Mass Index Results Form

1. Complete participant name and date.
2. Record computer calculated height in inches, weight in pounds, and BMI.

3. Place a checkmark (✓) in the row that corresponds with the calculated BMI result.
4. Review results and advice.
5. Leave form with participant.

Specimen Shipping and Handling Guidance

1. When to ship?

Review the table on the back of this page to determine when specimens should be shipped. Every drop-off location will have different cutoff times; if you don't know what the cut-off time is, **ask the agent!**

Remember, some non-FedEx shipping locations will take your shipment whenever you drop it off with them—even if the “real” FedEx courier has already made the last pick-up for the day. They will then hold the shipment until the next scheduled FedEx pick-up (which could be several days later if it is a weekend); meanwhile the specimens may be getting warm.

ALWAYS check with the agent at the time of drop-off to ensure that the shipment will arrive the next day. If it will not, take the HVK home with you and re-ice for shipment on the day of the next scheduled courier pick-up.

GuLF STUDY Home Visit Kit Shipping Instructions

Which Cohort?	What time of day is it?	What day of the week is it?						
		Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Active Follow-up AND Biomedical Surveillance Subcohorts	Before FedEx cutoff time	Send by FedEx as usual	Send by FedEx as usual	Send by FedEx as usual	Send by FedEx as usual	Send by FedEx using Saturday label	Hold until MONDAY and re-ice each morning	Hold until MONDAY and re-ice each morning
	After FedEx cutoff time	Hold until tomorrow and re-ice in morning	Hold until tomorrow and re-ice in morning	Hold until tomorrow and re-ice in morning	Hold until tomorrow and re-ice in morning. Send by FedEx using Saturday label	Hold until MONDAY and re-ice each morning	Hold until MONDAY and re-ice each morning	Hold until MONDAY and re-ice each morning

Steps to Follow After the Home Visit

Complete the Home Visit Time Log

1. Complete all fields in the Visit Log Spreadsheet with each visit in a new row.
2. Email weekly (Monday) as an attachment to Field Operations Manager and your Regional Manager with the following in the subject line: HVA # Home Visit Log

Spirometry Results

1. **RUN THIS PROGRAM ONCE A WEEK ON SUNDAY OR MONDAY TO UPLOAD YOUR SPIROMETRY DATA**
2. Double click the file_transfer.jar (*the application does not require VPN access).
3. When application opens, the user is presented with a Start button and output display window.
4. Select the Start button to begin the transfer process.
5. Upon successful completion the user will be prompted in the command with "All commands have run successfully"
6. If an Error were to occur the user will be alerted to call their project support staff.
7. A new spirometry file will be placed in the correct directory and the previous file placed in a backup directory for a set amount of time.

DatStat: Illume

1. Once you are home and connected to the internet you must login to Illume
2. Open on your PPT survey (baseline questionnaire) and SUBMIT
3. Open on your PPT specimen (baseline questionnaire specimen collection) and SUBMIT
4. Select the "Baseline Questionnaire" and SYNCHRONIZE
5. Select the "Baseline Questionnaire Specimen Collection" and SYNCHRONIZE

Distressed Participants

Program these important phone numbers into your Android

Alabama RM	251-272-2774
Florida RM	850-281-9878
Louisiana RM	504-579-3675
Texas RM	504-579-3675
Mississippi RM	228-364-3448
Steve Ramsey	919-886-0978
Lifeline Hotline	1-800-273-8255
Emergency Services	911

Definitions

1. **Passive Suicidal Thoughts:** the participant has thoughts or wishes about his/her death **in the absence of** thoughts about specific ways s/he could die or attempt suicide, plans for how s/he could die or attempt suicide, or intention of dying or attempting suicide
2. **Active Suicidal Thoughts:** the participant has thoughts or wishes about his/her death **combined with** thoughts about specific ways s/he could die or attempt suicide, plans for how s/he could die or attempt suicide, the intention of dying or attempting suicide, and the means to carry out that plan
3. **Passive Homicidal Thoughts:** the participant has thoughts or wishes about seriously harming someone else **in the absence of** thoughts about specific ways in which s/he could seriously harm another person, plans for how s/he could seriously harm another person, intentions of seriously harming another person
4. **Active Homicidal Thoughts:** the participant has thoughts or wishes about seriously harming someone else **combined with** thoughts about specific ways s/he could seriously harm another person, plans for how s/he could seriously harm another person, the intention of seriously harming another person, and the means to carry out that plan

Important

If a participant reports any of the issues defined above during any interactions with the HVA during the home visit or scheduling calls, the HVA will immediately refer to the scenario chart below and follow the instructions provided. Details of all incidents should be documented in the CAPI system and reported to project management staff immediately.

Scenario	Issue	Individual at Risk of Harm	Imminent Danger	Actions
1	Passive Suicidal Thoughts	Self	No	<ul style="list-style-type: none"> - Continue Home Visit activities - Strongly suggest they contact a health care professional and/or - Strongly suggest they call the national Lifeline hotline - Fill out an incident report
2	Active Suicidal Thoughts	Self	Possible or Yes	<ul style="list-style-type: none"> - End Home Visit activities - Strongly suggest the national Lifeline hotline be contacted together - If participant is unwilling to contact Lifeline hotline, call 911. - Once Lifeline or 911 is contacted, contact your Regional Manager and/or SRA Managers to inform them of the situation. - Fill out an incident report
3	Passive Homicidal Thoughts	Others	No	<ul style="list-style-type: none"> - Continue Home Visit activities - Contact your RM and/or SRA Managers and follow their direction. - Fill out an incident report
4	Active Homicidal Thoughts	Others	Possible Or Yes	<ul style="list-style-type: none"> - End Home Visit activities and immediately leave the home. - Once in a safe location, call 911 - Contact your RM and/or SRA Managers to inform them of the situation - Fill out an incident report